



APPENDIX A



DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE FACILITY
LICENSURE & CERTIFICATION
99 Chauncy Street
Boston, MA 02111

Invasive Cardiovascular Services Clinical Information & Attestation Form

INSTRUCTIONS: Submit this form when making an initial application for approval of Invasive Cardiovascular Services. Submit the completed form to:

Licensure Coordinator
Department of Public Health
Division of Health Care Facility Licensure & Certification
99 Chauncy St., 11th Floor
Boston, MA 02111

CONTACT INFORMATION

Hospital Name:			
Hospital Address:		Telephone #:	
		Fax #:	
Hospital Contact Person:		Title:	
Telephone #:		Email:	

ATTESTATION OF COMPLIANCE

Based upon full review of the licensure requirements at 105 CMR 130.900-.982, I attest that the above-named Hospital:

- ☐ Is operating an existing service in full compliance with the requirements at 105 CMR 130.915 as of March X, 2017; or
- ☐ Is a new program with capacity to be in full compliance with the requirements at 105 CMR 130.915;

and that all of the information provided in this document and supporting documentation is accurate and complete; that the Applicant is aware that the Department must be notified of any change in information, and that all other applicants, if any, have received copies of the application.

Signature of Hospital's authorized representative

Date

Typed/printed name of Hospital's authorized representative

Check all services for which the hospital is seeking approval (check all that apply):

- ☐ Diagnostic Cardiac Catheterization
- ☐ Diagnostic/Interventional Cardiac Catheterization
- ☐ Pediatric Cardiac Catheterization
- ☐ Electrophysiology



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PROGRAM COMPLIANCE**Directions**

In support of the attestation statement completed on p. 1 of this form, the following areas of state regulation must be addressed to obtain approval for a licensed hospital to operate Invasive Cardiovascular Services. Cardiac catheterization procedures shall not be performed in a satellite facility or a freestanding clinic.

Complete the appropriate column to indicate the compliance status for each item as of the date this form is completed:

Yes: Place a check in this box for items currently in compliance.

No: Place a check in this box for items not in compliance and for which the following have been submitted, subject to the Department's approval:

- Additional documentation in support of future compliance (including a proposed timeline); and/or
- A waiver request demonstrating the following:
 - That compliance will cause hardship;
 - That non-compliance will not jeopardize the health or safety of patients; and
 - Conditions in place to mitigate non-compliance.

GENERAL SERVICE REQUIREMENTS – APPLICABLE TO ALL HOSPITALS

Yes	No	105 CMR 130.900-.982 Requirement
❖ STAFF		
❖ Physician Director		
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director [130.940(A)] The hospital has designated a licensed physician director who shall have responsibility for the cardiac catheterization service.
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director – Board Certification [130.940(A)(1)] The physician director of the cardiac catheterization service that performs diagnostic procedures is board-certified in cardiovascular disease, and has training and experience in cardiac catheterization.
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director - Operation and Management [130.940(B)] The physician director of the service is responsible for the operational management of the environment and equipment.
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director - Policies and Procedures [130.940(B)] The physician director of the service has developed and implemented policies and procedures that include, at a minimum:
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Patient selection and exclusion criteria based on nationally accepted published guidelines of the American College of Cardiology/American Heart Association and the Heart Rhythm Society.
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Establishment and implementation of a quality assessment and performance improvement program.
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director - Credentialing [130.940(C)] The physician director of the invasive cardiology service, with the hospital administration, has established criteria for granting privileges to licensed physicians to perform cardiac catheterization procedures and will review and make recommendations regarding the applications for those privileges.
❖ Physicians		
<input type="checkbox"/>	<input type="checkbox"/>	Physicians [130.940(D)] The cardiac catheterization/electrophysiology service has on staff at least two physicians who are board-certified in cardiovascular disease and fully credentialed members of the hospital staff.
<input type="checkbox"/>	<input type="checkbox"/>	Physicians [130.940(D)] Each cardiac catheterization/electrophysiology physician is fully credentialed members of the hospital staff.
<input type="checkbox"/>	<input type="checkbox"/>	Privileges [130.940(D)(2)] The hospital has specifically defined the qualifications necessary for privileges to perform diagnostic and interventional/electrophysiology services.
❖ Assistants		
<input type="checkbox"/>	<input type="checkbox"/>	Assistants [130.940(E)] At least two persons assist the physician during the performance of all cardiac catheterization and electrophysiology procedures.



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<input type="checkbox"/>	<input type="checkbox"/>	Assistants-RN, NP, PA [130.940(E)] At least one assistant is either a registered nurse, nurse practitioner or physician assistant
<input type="checkbox"/>	<input type="checkbox"/>	Assistants-Equipment [130.940(F)] Appropriate staff is available to ensure all electronic and mechanical equipment is regularly checked and maintained in safe working order.
<input type="checkbox"/>	<input type="checkbox"/>	Assistants-Vascular Surgery [130.940(G)] A physician who has medical staff privileges in vascular surgery is available for consultation to the cardiac catheterization service staff consistent with written guidelines developed by the hospital.
<input type="checkbox"/>	<input type="checkbox"/>	Assistants-Radiology [130.940(H)] An individual qualified under the provisions of 105 CMR 120.020: <i>Registration of Radiation Machine Facilities and Services</i> is available for consultation for monitoring radiation safety for patients and personnel consistent with written guidelines developed by the hospital.
<input type="checkbox"/>	<input type="checkbox"/>	Assistants-ACLS [130.940(I)] All members of the cardiac catheterization/electrophysiology team maintain current certification in advanced cardiac life support.

❖ FACILITIES

		❖ Equipment and Supplies
<input type="checkbox"/>	<input type="checkbox"/>	Equipment Policies [130.950] The service is appropriately equipped and responsible for appropriate maintenance, pursuant to hospital policy.
<input type="checkbox"/>	<input type="checkbox"/>	Balloon Pump [130.950] The service makes an intra-aortic balloon pump available to the laboratory.
		❖ Space
<input type="checkbox"/>	<input type="checkbox"/>	Facility Guidelines [130.960(A)] Cardiac catheterization/electrophysiology laboratory meets the cardiac catheterization laboratory standards set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities, as referenced in 105 CMR 130.107.
<input type="checkbox"/>	<input type="checkbox"/>	Participant TB Testing [130.960(A)(1)] The patient recovery area is directly accessible from the procedure room and designed according to the standards applicable to recovery areas for ambulatory surgery from the <i>Guidelines for Design and Construction of Health Care Facilities</i> referenced in 105 CMR 130.107.

❖ CONTINUITY OF CARE

<input type="checkbox"/>	<input type="checkbox"/>	Policies and Procedures [130.962] The Hospital has developed and implemented policies and procedures that assure the continuity of the patient care, from the pre-catheterization teaching and obtaining of written consent through post-procedure care and discharge.
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❖ QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT

<input type="checkbox"/>	<input type="checkbox"/>	QAPI Program [130.965(A)] The service has established and will maintain an effective, ongoing, data-driven, evidence-based quality assessment and performance improvement (QAPI) program for all catheterization procedures, including electrophysiology procedures, if applicable, that focuses on patient outcomes while assessing individual operator clinical proficiency as well as overall laboratory safety and efficiency, including:
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Identification of quality measures, based on nationally accepted standards, that capture the quality of care provided and patient safety, [130.965(B)(1)]
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Collection and maintenance of data pertaining to these measures in a systematic manner, [130.965(B)(2)]
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Performs statistical analyses of the data for comparison with nationally accepted quality indicator benchmarks and longitudinally within the hospital on a routinely scheduled basis, [130.965(B)(3)]
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Analyzes comparison results and identify areas for improvement, and [130.965(B)(4)]
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Develops, implements and evaluates evidence-based improvement interventions to address the identified areas, and incorporate feedback for catheterization service staff on the effectiveness of the solutions and/or triggers further opportunities for improvement. [130.965(B)(5)]



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<input type="checkbox"/>	<input type="checkbox"/>	QAPI Assessments [130.965(C)] The QAPI program includes assessments of at least the following: <ul style="list-style-type: none"> • Appropriate patient selection (according to pre-established selection criteria, consistent with nationally accepted standards), [130.965(C)(1)] • The appropriateness of each cardiac catheterization or electrophysiology service procedure, [130.965(C)(2)] • Technical quality of the catheterization or electrophysiology service studies, [130.965(C)(3)] • Diagnostic accuracy and completeness of studies, and [130.965(C)(4)] • All catheterization or electrophysiology procedure-related complications and adverse outcomes (including infections) identified or reported, [130.965(C)(5)] • Number of cases requiring interhospital transfer and the reason for transfer, [130.965(C)(6)] • The number and percent of diagnostic cardiac catheterization procedures determined to be normal (<i>i.e.</i>, no disease or physiologically insignificant coronary stenosis), [130.965(C)(7)] • Patient experience measure data; and, [130.965(C)(8)]
<input type="checkbox"/>	<input type="checkbox"/>	National Data Registry Each cardiac catheterization service shall participate in a national data registry to help compare results and track complications. [130.965(C)]
<input type="checkbox"/>	<input type="checkbox"/>	Medical Records [130.965(D)] Medical records include at a minimum the following information: <ul style="list-style-type: none"> • type of procedure performed • indication for procedure, • time course of procedural events,
<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • time and dose of all medications administered, • fluoroscopy time, • all catheter sheaths and special guide wires used, • pertinent hemodynamic and/or electrophysiologic data, • a detailed summary of the procedure, and • and a description of the angiographic or electrophysiologic findings and clinical recommendations.
❖ Quality Reporting		
<input type="checkbox"/>	<input type="checkbox"/>	QAPI Reports [130.965(E)] The hospital maintains quarterly written reports of QAPI findings, recommended actions, progress on implementation and supporting data, which is available for Department review upon request.
<input type="checkbox"/>	<input type="checkbox"/>	Reporting Submission [130.970] The hospital will submit information regarding volume of procedures, patient outcomes and utilization to the Department upon request.
❖ Minimum Workload		
<input type="checkbox"/>	<input type="checkbox"/>	Minimum Caseload Volume (Existing Service) [130.935] The hospital has maintained the specified minimum annual caseload volume.
<input type="checkbox"/>	<input type="checkbox"/>	Minimum Caseload Volume (New Service) [130.935] The hospital has submitted documentation demonstrating a plan to achieve and maintain the service volume minimum.

SPECIAL SERVICE REQUIREMENTS – COMPLETE AS APPLICABLE**❖ CARDIAC CATHETERIZATION/ELECTROPHYSIOLOGY SERVICES WITHOUT CARDIAC SURGERY**If hospital license includes cardiac surgery services, check box and DO NOT complete this section ☐

❖ Prerequisite for Cardiac Catheterization/Electrophysiology Services without Cardiac Surgery		
<input type="checkbox"/>	<input type="checkbox"/>	Collaboration Agreement [130.975] Hospital maintains a current written collaboration agreement with at least one tertiary hospital with a cardiac surgery program, including all of the following: <ul style="list-style-type: none"> • Guidelines for selection of patients appropriate for cardiac catheterization at the hospital without cardiac surgery • Provisions for emergency and routine transfer of patients including timely transfer of appropriate patient



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<input type="checkbox"/>	<input type="checkbox"/>	information. Language shall be included that describes the agreed upon cardiac catheterization image standard, to avoid redundant catheterization
<input type="checkbox"/>	<input type="checkbox"/>	• Provisions that specify that cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency
<input type="checkbox"/>	<input type="checkbox"/>	• Provisions that specify the responsibility for arranging transportation to the receiving hospital.
<input type="checkbox"/>	<input type="checkbox"/>	• Provisions for joint quality assurance reviews.
<input type="checkbox"/>	<input type="checkbox"/>	• Provisions for joint training and ongoing education of staff.
<input type="checkbox"/>	<input type="checkbox"/>	• Explicit description of responsibilities of each party to the agreement.

❖ INTERVENTIONAL CARDIAC CATHETERIZATION SERVICE REQUIREMENTS

If hospital is applying for diagnostic services ONLY, check box and do NOT complete this section ☐

<input type="checkbox"/>	<input type="checkbox"/>	❖ Physician Director
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director – Board Certification [130.940(A)(2)] The physician director of the cardiac catheterization service that performs interventional procedures is board certified in interventional cardiology.
<input type="checkbox"/>	<input type="checkbox"/>	❖ Physicians
<input type="checkbox"/>	<input type="checkbox"/>	Physicians [130.940(D)(1)] Physicians performing interventional cardiac catheterization procedures are board-certified in interventional cardiology.
<input type="checkbox"/>	<input type="checkbox"/>	Physicians-only answer if “no” to above. [130.940(D)(1)(a)] If “no”, physician is within 12 months of completing fellowship in interventional cardiology, and, until board certification, will only perform procedures under board certified supervisor who performs at least 125 procedures per year.

❖ PEDIATRIC CARDIAC CATHETERIZATION SERVICE REQUIREMENTS

If hospital is NOT applying for pediatric services, check box and do NOT complete this section ☐

<input type="checkbox"/>	<input type="checkbox"/>	❖ Prerequisite for Pediatric Cardiac Catheterization Services
<input type="checkbox"/>	<input type="checkbox"/>	Pediatric Service [130.921] The hospital has a licensed Level III pediatric service.

❖ ELECTROPHYSIOLOGY SERVICE REQUIREMENTS

If hospital is NOT applying for electrophysiology services, check box and do NOT complete this section ☐

<input type="checkbox"/>	<input type="checkbox"/>	❖ Physician Director
<input type="checkbox"/>	<input type="checkbox"/>	Physician Director – Board Certification (Electrophysiology) [130.940(A)(3)] The physician director of the cardiac catheterization service that performs diagnostic and interventional/therapeutic electrophysiology procedures (excluding those cardiac catheterization services that only implant pacemakers and perform no other electrophysiology procedures) is board-certified in clinical cardiac electrophysiology (CCEP).
<input type="checkbox"/>	<input type="checkbox"/>	❖ Physicians
<input type="checkbox"/>	<input type="checkbox"/>	Physicians-Electrophysiology Services [130.940(D)(2)] Electrophysiology services are performed by physicians board-certified in cardiovascular disease with training in electrophysiology services and cardiac arrhythmias.
<input type="checkbox"/>	<input type="checkbox"/>	Physicians-Electrophysiologists [130.940(D)(2)(a)] Physicians performing electrophysiology procedures (except for those physicians who only implant pacemakers and cardioverter-defibrillators and perform no other electrophysiology procedures) are board-certified in clinical cardiac electrophysiology.
<input type="checkbox"/>	<input type="checkbox"/>	Physicians-Non-Electrophysiologist [130.940(D)(2)(b)] Non-electrophysiologists wishing to implant cardioverter-defibrillators and cardiac resynchronization therapy devices are trained in an American Council for Graduate Medical Education approved fellowship program and have passed a competency exam offered by the International Board of Heart Rhythm Examiners.
<input type="checkbox"/>	<input type="checkbox"/>	❖ Prerequisite for Electrophysiology Services
<input type="checkbox"/>	<input type="checkbox"/>	Cardiac Catheterization Services [130.980] The hospital is approved to provide cardiac catheterization services.
<input type="checkbox"/>	<input type="checkbox"/>	Procedures (only answer if “no” to above) [130.980] If “no”, the <u>only</u> procedures hospital will perform are implanting pacemakers, defibrillators and monitoring devices.